

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1

of 2

Complete if Known

Application Number	NOT YET ASSIGNED
Filing Date	ON EVEN DATED HEREWITH
First Named Inventor	Carlo RICCARDI
Group Art Unit	
Examiner Name	
Attorney Docket Number	RICCARDI=1A

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	AA	BARRETT et al., Coordinate regulation of glucocorticoid receptor and c-jun gene expression is cell type-specific and exhibits differential hormonal sensitivity for down- and up-regulation, <u>Biochemistry</u> 35(30):9746-9753 (1996)	
	AB	D'ADAMIO et al., A new dexamethasone-induced gene of the leucine zipper family protects T lymphocytes from TCR/CD3-activated cell death, <u>Immunity</u> , 7(6):803-812 (1997)	
	AC	FENG et al., Glucocorticoid and progesterone inhibit involution and programmed cell death in the mouse mammary gland, <u>J. Cell Biol.</u> , 131(4):1095-1103 (1995)	
	AD	JAY et al., Cloning of the human homologue of the TGF beta-stimulated clone 22 gene, <u>Biochem. Biophys. Res. Commun.</u> , 222(3):821-826 (1996)	
	AE	JEHN et al., Gene regulation associated with apoptosis, <u>Crit. Rev. Eukaryot. Gene Expr.</u> , 7(1-2):179-193 (1997)	
	AF	KATO et al., Inhibition by dexamethasone of human neutrophil apoptosis <i>in vitro</i> , <u>Nat Immun.</u> , 14(4):198-208 (1995)	
	AG	KING et al., A targeted glucocorticoid receptor antisense transgene increases thymocyte apoptosis and alters thymocyte development, <u>Immunity</u> , 3(5):647-656 (1995)	
	AH	OHTA et al., Mechanism of apoptotic cell death of human gastric carcinoma cells mediated by transforming growth factor beta, <u>Biochem. J.</u> , 324 (Pt 3):777-782 (1997)	
	AI	SILLARD et al., A novel 77-residue peptide from porcine brain contains a leucine-zipper motif and is recognized by an antiserum to delta-sleep-inducing peptide, <u>Eur. J. Biochem.</u> , 216(2):429-436 (1993)	
	AJ	SHIBANUMA et al., Isolation of a gene encoding a putative leucine zipper structure that is induced by transforming growth factor beta 1 and other growth factors, <u>J. Biol. Chem.</u> , 267(15):10219-10224 (1992)	
	AK	VOGEL et al., hDIP—a potential transcriptional regulator related to murine TSC-22 and Drosophila shortsighted (shs)—is expressed in a large number of human tissues, <u>Biochim. Biophys. Acta</u> , 1309(3):200-204 (1996)	
	AL	YANG et al., Fas and activation-induced Fas ligand mediate apoptosis of T cell hybridomas: inhibition of Fas ligand expression by retinoic acid and glucocorticoids, <u>J. Exp. Med.</u> , 181(5):1673-1682 (1995)	

Examiner
SignatureDate
Considered

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2

of 2

Complete if Known

Application Number	NOT YET ASSIGNED
Filing Date	ON EVEN DATED HEREWITH
First Named Inventor	Carlo RICCARDI
Group Art Unit	
Examiner Name	
Attorney Docket Number	RICCARDI=1A

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	AM	Muller OG, Parnova RG, Centeno G, Rossier BC, Firsov D, Horisberger JD., Mineralocorticoid effects in the kidney: correlation between alphaENaC, GILZ, and Sgk-1 mRNA expression and urinary excretion of Na ⁺ and K ⁺ . <u>J Am Soc Nephrol</u> . 2003 May;14(5):1107-15.	
	AN	Shi X, Shi W, Li Q, Song B, Wan M, Bai S, Cao X., A glucocorticoid-induced leucine-zipper protein, GILZ, inhibits adipogenesis of mesenchymal cells. <u>EMBO Rep</u> . 2003 Apr;4(4):374-80.	
	AO	Ingram WJ, Wicking CA, Grimmond SM, Forrest AR, Wainwright BJ., Novel genes regulated by Sonic Hedgehog in pluripotent mesenchymal cells. <u>Oncogene</u> . 2002 Nov 21;21(53):8196-205.	
	AP	Berrebi D, Bruscoli S, Cohen N, Foussat A, Migliorati G, Bouchet-Delbos L, Maillot MC, Portier A, Couderc J, Galanaud P, Peuchmaur M, Riccardi C, Emilie D., Synthesis of glucocorticoid-induced leucine zipper (GILZ) by macrophages: an anti inflammatory and immunosuppressive mechanism shared by glucocorticoids and IL-10. <u>Blood</u> . 2003 Jan 15;101(2):729-38. Epub 2002 Sep 12.	
	AQ	Ayrolidi E, Zollo O, Macchiarulo A, Di Marco B, Marchetti C, Riccardi C., Glucocorticoid-induced leucine zipper inhibits the Raf-extracellular signal-regulated kinase pathway by binding to Raf-1. <u>Mol Cell Biol</u> . 22(22):7929-41 Nov 2002	
	AR	Riccardi C, Bruscoli S, Ayrolidi E, Agostini M, Migliorati G., GILZ, a glucocorticoid hormone induced gene, modulates T lymphocytes activation and death through interaction with NF-kB. <u>Adv Exp Med Biol</u> . 495:31-9, 2001.	
	AS	Ayrolidi E, Migliorati G, Bruscoli S, Marchetti C, Zollo O, Cannarile L, D'Adamio F, Riccardi C., Modulation of T-cell activation by the glucocorticoid-induced leucine zipper factor via inhibition of nuclear factor kappaB. <u>Blood</u> . 2001 Aug 1;98(3):743-53.	
	AT	Mittelstadt PR, Ashwell JD., Inhibition of AP-1 by the glucocorticoid-inducible protein GILZ., <u>J Biol Chem</u> . 2001 Aug 3;276(31):29603-10. Epub 2001 Jun 07.	
	AU	Cannarile L, Zollo O, D'Adamio F, Ayrolidi E, Marchetti C, Tabilio A, Bruscoli S, Riccardi C., Cloning, chromosomal assignment and tissue distribution of human GILZ, a glucocorticoid hormone-induced gene. <u>Cell Death Differ</u> . 2001 Feb;8(2):201-3.	
	AV	Robert-Nicoud M, Flahaut M, Elalouf JM, Nicod M, Salinas M, Bens M, Doucet A, Wincker P, Artiguenave F, Horisberger JD, Vandewalle A, Rossier BC, Firsov D., Transcriptome of a mouse kidney cortical collecting duct cell line: effects of aldosterone and vasopressin., <u>Proc Natl Acad Sci U S A</u> . 2001 Feb 27;98(5):2712-6. Epub 2001 Feb 20.	
	AW	Riccardi C, Zollo O, Nocentini G, Bruscoli S, Bartoli A, D'Adamio F, Cannarile L, Delfino D, Ayrolidi E, Migliorati G. Glucocorticoid hormones in the regulation of cell death. <u>Therapie</u> . 2000 Jan-Feb;55(1):165-9.	
	AX	Riccardi C, Cifone MG, Migliorati G., Glucocorticoid hormone-induced modulation of gene expression and regulation of T-cell death: role of GTR and GILZ, two dexamethasone-induced genes., <u>Cell Death Differ</u> . 1999; 6: 1182-9. (Comment in: <u>Cell Death Differ</u> . 1999 6: 1144-5.)	
	AY	D'Adamio F, Zollo O, Moraca R, Ayrolidi E, Bruscoli S, Bartoli A, Cannarile L, Migliorati G, Riccardi C., A new dexamethasone-induced gene of the leucine zipper family protects T lymphocytes from TCR/CD3-activated cell death. <u>Immunity</u> . 1997 Dec;7(6):803-12.	

Examiner
SignatureDate
Considered

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: RICCARDI=1A

In re Application of:)	Conf. No.:
)	
RICCARDI et al.)	Art Unit:
)	
Appln. No.: NOT YET ASSIGNED)	Examiner:
)	
Filed: ON EVEN DATED HERewith)	Washington, D.C.
)	
For: INTRACELLULAR MODULATORS)	July 31, 2003
OF APOPTOPIC CELL DEATH)	
PATHWAYS)	

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir :

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed:

(Check one of the boxes A-D)

☒ A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.

☒ B. before the mailing date of a first Office action on the merits or before the mailing of a first Office action after the filing of a Request for Continued Examination under 37 C.F.R. §1.114.

☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below).

(Check one of the boxes "i" and "ii" below:)

☐ i. Counsel certifies that, upon information and belief, each item of information listed herein was either

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in §1.56(c) more than three months prior to the filing of this IDS.

(use one and delete other of following)

☐ ii. A check (check no. _____) for the fee set forth in §1.17(p), presently believed to be \$180, is enclosed. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035.

☐ ii. Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth

in §1.17(p), presently believed to be \$180.. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035.

☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant(s) state as follows under 37 CFR §1.97(e) for consideration of this IDS, that, upon information and belief, each item of information listed herein was either

(Check one of the boxes "a" and "b" below)

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in §1.56(c) more than three months prior to the filing of this IDS.

(use one and delete other of following and this note) A check (check no. _____) for/ Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in §1.17(i), presently believed to be \$180 is enclosed. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035.

2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., Form PTO/SB/08A) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached.

(check boxes A and/or B and fill in blanks, if appropriate)

☐ A. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with §1.98(c), only a copy of each of the latter documents is enclosed.

☒ B. Documents AA-AL were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

09/403,861, filed February 11, 2000

Applicant(s) identifies these documents by attaching hereto copies of the forms PTO-892 and PTO-1449 (or PTO/SB/08A) from the files of the prior application(s) or a fresh PTO-1449 (or PTO/SB/08A) listing these documents, and request that they be considered and made of record in accordance with §1.98(d). Per 37 CFR §1.98(d), copies of these documents need not be filed in this application.

3. Document(s) _____ is (are) not in the English language. In accordance with §1.98(a)(3), Applicant(s) states:

☐ An English translation of each document _____ (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.

☐ A concise explanation of the relevance of document(s) _____ is found in the attached _____ search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

☐ A concise explanation of the relevance of document(s) _____ is set forth as follows:

(insert concise explanation of relevance)

[] A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.

[] A concise explanation of document(s) _____ can be found on the attached sheet.

4.No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

5.Other information being provided for the examiner's consideration follows:

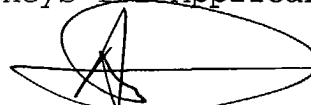
(insert other information)

6. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant(s) reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

BROWDY AND NEIMARK
Attorneys for Applicant(s)

By:



Allen C. Yun
Reg. No. 37,971

ACY:pp
624 Ninth Street, N.W., Suite 300
Washington, D.C. 20001-5303
Telephone: (202) 628-5197
Facsimile: (202) 737-3528